Calithera Biosciences Reports Fourth Quarter 2017 Financial Results and Recent Highlights

March 8, 2018

-Calithera to Webcast Corporate Update on March 8, 2018

SOUTH SAN FRANCISCO, Calif., March 08, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, announced today its financial results for the fourth quarter and year ended December 31, 2017. As of December 31, 2017, cash, cash equivalents and investments totaled $186.2 million.

“2017 was a transformative year for Calithera as we advanced each of our internally discovered first-in-class, small molecule onco-metabolism clinical candidates into broad clinical programs and announced a partnership with Incyte.” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “In 2018, we will be enrolling two randomized placebo-controlled trials of our oral glutaminase inhibitor for the treatment of patients with renal cell carcinoma and a Phase 2 trial for the treatment of patients with triple negative breast cancer. INCB001158, an inhibitor of arginase, will be in evaluated in three broad clinical trials for the treatment of patients with solid tumors in combination with a PD-1 inhibitor, chemotherapy, and epacadostat/PD-1 inhibitor, respectively.”

Fourth Quarter 2017 and Recent Highlights

CB-839

- **Presented Results of CB-839 in Combination with Cabozantinib in Renal Cell Carcinoma; Randomized Phase 2 Trial Planned.** In February 2018, we presented preliminary results of the Phase Ib trial of CB-839 in combination with cabozantinib, an oral tyrosine kinase inhibitor at the 2018 Genitourinary Cancer Symposium. Preliminary results showed the combination demonstrated 40% overall response rate in advanced clear cell RCC patients, and 100% disease control with the safety profile of CB-839 plus cabozantinib generally consistent with that of cabozantinib monotherapy. On the basis of this efficacy and safety data, we plan to initiate a randomized double-blind placebo controlled trial in approximate 300 clear cell renal cell carcinoma patients who have previously received one or two prior lines of therapy. The Phase 2 trial, known as CANTATA, is planned to begin in the second quarter of 2018 and it is expected to take approximately two years to reach the primary endpoint analysis of progression free survival.

- **Presented Results of CB-839 in Combination with Nivolumab.** In November 2017, we announced initial data from the ongoing trial of CB-839 in combination with nivolumab, in patients with melanoma, renal cell carcinoma and non-small cell lung cancer. Responses were observed in three melanoma patients who were progressing on a checkpoint inhibitor at study entry, and disease stabilization was observed in patients with non-small cell lung cancer and renal cell carcinoma patients that had disease progression on a checkpoint inhibitor immediately prior to starting the CB-839/nivolumab combination. The collaboration with Bristol-Myers Squibb was expanded, and a joint development committee was established to guide the development and regulatory strategy.

- **Presented Results of CB-839 in Combination with Paclitaxel for the Treatment of Triple Negative Breast Cancer.** In December 2017, we presented updated clinical data from a Phase 2 expansion cohort of patients with triple negative breast cancer receiving CB-839 in combination with paclitaxel. Among all evaluable patients treated with CB-839 doses of at least 600 mg bid (n=37), there were 8 partial responses (22%) and disease control in 22 patients (59%). Exploratory biomarker analysis showed a trend for the strongest clinical benefit occurring in patients with desmoplastic stromal gene expression signatures. We plan to present an update on our TNBC development program in the fourth quarter of 2018.

INCB001158

- **INCB001158 Initiated Combination Dosing.** In October 2017, the first patient was treated in the Phase I cohort of INCB001158 dosed in combination with Keytruda® (pembrolizumab), an anti-PD1 immune checkpoint inhibitor. INCB001158 is currently being evaluated in two Phase 1/2 clinical trials and a third trial is expected to begin in the first half of 2018.

Corporate

- **Augmented Board of Directors and Management Team.** In September 2017, Calithera appointed Blake Wise, President and Chief Operating Officer of Achaogen, to the company’s Board of Directors, and Sumita Ray as General Counsel.

Selected Fourth Quarter 2017 Financial Results

Cash, cash equivalents and investments totaled $186.2 million at December 31, 2017.

Collaboration revenue for the full year 2017 was $26.0 million, compared with zero in the prior year, and represents the portion of deferred revenue recognized from the Company's collaboration and license agreement with Incyte. Collaboration revenue for the fourth quarter of 2017 was $7.3 million.

Research and development expenses for the full year 2017 were $43.1 million, compared with $27.7 million in the prior year. The increase of $15.4 million in 2017 was due to an increase in the CB-839 program to support our new and ongoing clinical trials, including our two Phase 2 trials, as well as investment in our early stage research programs, offset by a decrease in the INCB001158 program, primarily due to Incyte's co-funding of development costs. Research and development expenses for the fourth quarter of 2017 were $15.5 million, compared to $6.6 million for the same period last year.

General and administrative expenses for the full year 2017 were $12.5 million, compared with $10.6 million in the prior year. The increase of $1.9 million in 2017 was primarily due an increase in professional services, including activities to support our collaboration and license agreements and Phase 2 clinical trials, and higher personnel-related costs. General and administrative expenses for the fourth quarter of 2017 were $3.3 million, compared to $3.0 million for the same period last year.

Net loss from operations for the three months and year ended December 31, 2017 was $11.0 million and $27.8 million, respectively.

Financial Guidance for 2018

Calithera expects its cash, cash equivalents and investments will be between $105 and $115 million at the end of 2018, and be sufficient to meet its current operating plan through 2020, exclusive of any new collaborations or partnerships, milestone payments, additional equity financings or other new sources.

Conference Call Information

Calithera will webcast a clinical update on CB-839 on Thursday, March 8th at 4:30 p.m. Eastern Time/ 1:30 p.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 3398144. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. The webcast will be recorded and available for replay on Calithera's website for 30 days.

About Calithera

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's lead product candidate, CB-839, is a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in Phase 2 clinical trials in combination with standard of care agents. INCB001158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells, known as cytotoxic T-cells. INCB001158 is being developed in collaboration with Incyte Corporation and is currently in Phase 1/2 clinical trials. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to the timing of Calithera's clinical trials, Calithera's collaborations with Incyte and and Bristol-Myers Squibb, Calithera's ability to fund its clinical programs, Calithera's receipt of clinical data from its clinical trials, and Calithera's financial guidance for 2018. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's business can be found in Calithera's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

Calithera Biosciences, Inc.
Selected Consolidated Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Collaboration revenue	$ 7,254	$ —	$ 25,955	$ —
Total revenue	7,254	—	25,955	—
Operating expenses:				
Research and development	15,496	6,593	43,111	27,748
General and administrative	3,300	3,011	12,530	10,586

Total operating expenses	18,796	9,604	55,641	38,334
Loss from operations	(11,542)	(9,604)	(29,686)	(38,334)
Interest income, net	568	84	1,860	330
Net loss	$ (10,974)	$ (9,520)	$ (27,826)	$ (38,004)
Net loss per share, basic and diluted	$ (0.31)	$ (0.45)	$ (0.84)	$ (1.95)
Weighted average common shares used to compute net loss per share, basic and diluted	35,560	21,045	32,951	19,486

Calithera Biosciences, Inc.
Selected Consolidated Balance Sheet Financial Data
(in thousands)
(unaudited)

	December 31, 2017	December 31, 2016
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 186,154	$ 51,781
Working capital	128,640	49,108
Total assets	192,455	54,796
Deferred revenue	31,045	—
Total liabilities	42,148	4,890
Accumulated deficit	(150,333)	(122,502)
Total stockholders' equity	150,307	49,906

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Source: Calithera Biosciences, Inc.